



01/18/05

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant: Paul M. Scopton Confirmation No.: 8323
Serial No.: 09/498,104 Examiner: M. DeSanto
Filing Date: February 4, 2000 Group Art Unit: 3763
Docket No.: 1001.1375101 Customer No.: 28075
For: FLUID INJECTABLE SINGLE OPERATOR EXCHANGE CATHETERS AND
METHODS OF USE

TRANSMITTAL SHEET

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certified that this paper or papers, as described herein are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of: EV 314496282 US, in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 14th day of January 2005.

By Kathleen L. Boekley
Kathleen L. Boekley

We are transmitting herewith the attached:

Amendment No additional claim fee required The claim fee has been calculated as shown:

CLAIMS AS AMENDED							
				SMALL ENTITY		OTHER	
	REMAINING CLAIMS	HIGHEST PAID	EXTRA	RATE	ADD'L FEE	RATE	ADD'L FEE
TOTAL CLAIMS	-	=		X 25 =	\$	X 50 =	\$
INDEPENDENT CLAIMS	-	=		X 100 =	\$	X 200 =	\$
() FIRST MULTIPLE DEPENDENT CLAIM				+ 180 =	\$	+ 360 =	\$
TOTAL				\$		\$	

Small entity status of this application under 37 C.F.R. §§ 1.9 and 1.27 has been established.

[] A check in the amount of \$ _____ is enclosed. Itemization:

Fee Code _____ \$

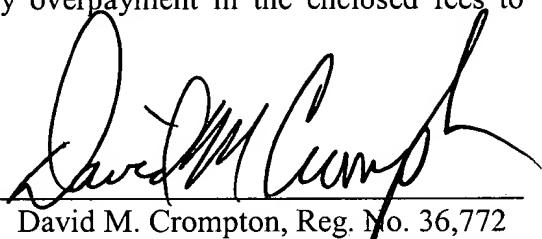
Fee Code _____ \$

Fee Code _____ \$

[XX] Other: REPLY BRIEF IN TRIPPLICATE.

[XX] Return Receipt Postcard (MPEP 503).

[XXXX] Please charge any deficiencies or credit any overpayment in the enclosed fees to
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By: 
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P A T E N T

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REPLY BRIEF UNDER 37 C.F.R. § 1.193

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certified that this paper or papers, as described herein are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of: EV 314496282 US, in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 14th day of January 2005.

By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 1.193, Appellant hereby submits this Reply Brief in triplicate in response to the Examiner's Answer filed on December 2, 2004. Remarks begin on page 2.

REMARKS

1. Claims 1-5 and 7 are patentable over Sirhan (U.S. Patent No. 5,984,945).

In the Response to Argument section, the Examiner asserts that the claims do not state that the entire guidewire lumen extension has to be external to or parallel to the shaft. MPEP § 2111 states that during examination, "the pending claims must be given their broadest reasonable interpretation consistent with the specification", and that the "broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." Independent claim 1 recites a tubular member that (1) is connected to the shaft, (2) extends proximally from the guidewire port, (3) is external to but parallel with the shaft, and (4) is axially aligned with the guidewire lumen.

Appellants submit that one of ordinary skill in the art would not interpret the distal tubular section 12 of Sirhan as anticipating each and every element of independent claim 1, as is asserted by the Examiner. Sirhan does not disclose tubular section 12 as connected to shaft 27. At best, tubular section 12 fits within shaft 27, as shown in FIG. 15. Appellants submit that one of ordinary skill in the art would not reasonably interpret the phrase "the guidewire lumen extension being external to but parallel with the shaft" as a tubular member that is either parallel to but inside the shaft or external to but not parallel, as is described by Sirhan. The Examiner's interpretation of the claim is not consistent with the interpretation that those skilled in the art would reach.

With respect to claim 3, the Examiner asserts that the term "about" is interpreted as "reasonably close to" in accordance with the Webster's online dictionary. Appellant submits that the term "about" must be read in context and given the ordinary and customary meaning attributed to it by those of ordinary skill in the art. Claim 3 recites the phrase "tubular member is disposed about the shaft." MPEP § 111.01 states:

Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003).

Appellants submit that the second definition listed for "about" on the Webster's online dictionary printout, "on all sides: around", is the ordinary and customary meaning given the term in the phrase "disposed about" by those of ordinary skill in the art. MPEP § 2111.01 also states:

It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003) (Dictionary definitions were used to determine the ordinary and customary meaning of the words "normal" and "predetermine" to those skilled in the art. In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor.)

Appellants submit that because the term "about" is recited in the claim in the phrase "disposed about", the ordinary and customary meaning of the phrase must be used, and in this context that meaning is "on all sides; around" as set forth in the second definition from the printout provided by the Examiner.

Regarding claim 4, the Examiner asserts that Sirhan teaches the distal end fluidly sealed about the shaft, since any fluid that exits the guidewire lumen extension has to be transferred to the shaft. Appellants assert that the Examiner's interpretation of the claim language is inconsistent with that of one of ordinary skill in the art. Sirhan clearly shows the distal end of tubular member 12 disposed within shaft 27. See FIG. 15.

The Examiner asserts that there is no structure associated with claim 5. Appellants respectfully disagree. The claim recites the proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein. The claim thus recites a structure that restricts flow about the guidewire. Such language provides both a function and structural limitation, which is not taught or suggested by Sirhan. Sirhan does not teach, and the figures do not illustrate, any structure in tubular member 12 that restricts the flow about the guidewire. The Examiner's statement that since the guidewire lumen extension is smaller than the guidewire lumen, it is inherently sized to restrict the guidewire is not understood. Sirhan merely show tubular member 12 fitting inside shaft 27, and a guidewire fitting inside tubular member 12. Appellants submit that there is nothing inherent in this structure that would restrict flow about the guidewire.

Sirhan thus does not teach each and every limitation of the instant claims, as is required for anticipation under 35 U.S.C. §102. Withdrawal of the rejection is respectfully requested.

2. Claims 1-5, 7, 10-13, and 15 are patentable over Crittenden et al. (U.S. Patent No. 4,988,356).

In the Response to Arguments section, the Examiner states that the arguments in section B of Appellants' Brief seem to be drawn to the slit, and as this is not what the Examiner has determined as the ports, the arguments are not relevant. Appellants have carefully reviewed the prosecution history for this application, and the current Examiner's Answer is the first time the Examiner has pointed out the elements and corresponding reference numbers in Crittenden et al. that are considered to anticipate the proximal and distal guidewire ports of the instant claims. In every previous office action, the Examiner merely asserted that Crittenden et al. disclosed the elements of the claim without any indication of corresponding reference numbers. The reason Appellants' arguments were directed to the slit is that the slit was the only structure in Crittenden et al. that appeared to be close to a port, and without further explanation from the Examiner, Appellants were left with making an assumption in order to present arguments.

Appellants submit that the Examiner's interpretation of Crittenden et al. is contrary to the actual teachings of the reference. Crittenden et al. teach catheter 10 having longitudinal slit 28 extending through passageway 46 in the guide member 12, with flaps of the split catheter separated as they are drawn past the distal end 50 of tube 48 and spreader 54. See column 4, lines 57-62, column 6, lines 56-59, and FIG. 7. Crittenden et al. thus clearly do not teach reference number 50 as a guidewire port. Crittenden et al. teach a catheter with a longitudinal slit and a guide member that is used to open the slit to exchange catheters on the guidewire.

Crittenden et al. thus fail to teach each and every limitation of independent claims 1 and 10 and, therefore, also fail to teach the limitations of the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

3. Claims 1-5, 7-9, 10-13, and 15-17 are patentable over Horzewski et al. (U.S. Patent No. 4,771,777).

The Examiner argues that the structural elements of the claims are seen in figures 1 and 4 of Horzewski et al. Independent claim 1 recites a tubular member connected to the shaft and extending proximally from the proximal guidewire port. Horzewski et al. do not teach this structure. As is clearly shown in FIG. 4, Horzewski et al. teach removable slit sheath 71 disposed at a distance from proximal guidewire port 47. The Examiner argues that this structure meets the claim limitation "extends proximally from." As stated above, MPEP § 2111.01 states

that claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Appellants submit that one of ordinary skill in the art would not interpret Horzewski et al.'s teaching of sheath 71 spaced apart from port 47, as shown in FIG. 4, as extending proximally from the port.

The Examiner next argues that the phrase "in fluid communication" encompasses a situation in which if fluid were injected into the tubular member (assumed to be reference 71 in Horzewski et al. FIG. 4), some of that fluid would flow into the guidewire lumen (assumed to be reference 46). The Examiner also argues that the tubular member is capable of transferring fluid to the guidewire lumen. Appellants submit that such interpretations are inconsistent with the teachings of Horzewski et al. and are contrary to the interpretation of one of ordinary skill in the art. The phrase "in fluid communication" has a specific meaning to one of skill in the catheter art, and that meaning does not include a situation where there is the possibility that some fluid from one tubular structure might flow into another, spaced apart, tubular structure.

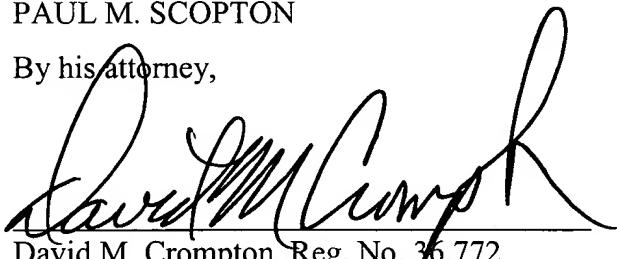
Regarding claims 3 and 5, see the arguments above. Horzewski et al. do not teach, and the figures do not illustrate, any structure in sheath 71 that restricts the flow about the guidewire. Horzewski et al. fail to teach or contemplate the limitations of the claims. Withdrawal of the rejection is respectfully requested.

For the reasons stated above, the rejections of claims 1-5, 7-13, and 15-17 under 35 U.S.C. §§ 102(b) and 102(e) should be reversed.

Respectfully submitted,

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Date: 1/14/05